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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/900,450	07/09/2001	Luciano Pedrini	P66652US0	4235

7590 12/04/2002

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EXAMINER
KIM, SUN U

ART UNIT	PAPER NUMBER
1723	7

DATE MAILED: 12/04/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

AS-7

Office Action Summary

Application No.	Applicant(s)
09/900,450	Pedrini et al.
Examiner	**Art Unit**
John Kim	1723

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on *Jul 9, 2001*.

2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *1-13* is/are pending in the application.

4a) Of the above, claim(s) _____ is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) *1-13* is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) ☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☒ All b) ☐ Some* c) ☐ None of:

1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) ☐ The translation of the foreign language provisional application has been received.

15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 4
4) ☐ Interview Summary (PTO-413) Paper No(s). _____
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

1. Examiner requests applicants to submit English translated copies of the foreign prior arts in information disclosure statement filed on 10/15/01 if available.

2. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the valves in the supply lines (12, 14) must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

3. Claims 1-13 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Applicants do not sufficiently describe how the operational and/or blood parameters such as the transmembrane pressure (TMP), blood density and/or hematocrit value (HKT) are controlled in relation to one of the infusion rates of the substitution solutions.

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 1-13 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Recitations of "the control" in claim 1, "the blood circuit" in claim 7, "the dialysis-fluid circuit" in claim 9 lack positive antecedent basis.

6. Claim 1 provides for the use of at least one of infusion rates of the substitution solutions, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claim 1 is rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd. v. Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless -
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

9. Claims 1, 4, 7-8 and 12 are rejected under 35 U.S.C. 102(b) as being anticipated by WO 98/50091. WO 98/50091 teaches method and device for controlling a blood purifying device

including hemofilter and hemodialyzer wherein a control unit (9-14) takes signals from weighing means (5, 6, 7) for measuring substitution product from reservoirs (15, 16) and ultrafiltrate (17) and adjusts the instantaneous flow rates of blood, ultrafiltrate and the substitution products by monitoring substitution pumps upstream and/or downstream of the blood purifying device (see abstract; figure 1).

10. Claims 2 and 9-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 98/50091 as applied to claim 1 and 7 above, and further in view of "Hemodialysis Machines and Monitors" by Polaschegg et al. in Replacement of Renal Function by Dialysis edited by C. Jacobs et al, pages 334-373 (hereinafter referred to as Polaschegg et al). WO 98/50091 teaches method and device for controlling a blood purifying device as described above. Claims 2 and 9-11 essentially differ from the method and apparatus of WO 98/50091 in reciting that the operational and/or blood parameters are TMP, blood density and/or HKT and associated sensors for measuring the claimed parameters. Polaschegg et al teach that the ultrafiltration rate is controlled by the transmembrane pressure which are measured by pressure sensors in extracorporeal circuit and/or dialysis circuit (see figure 20; pages 348-349). Polaschegg et al further teach that ultrafiltration rate can be controlled by monitoring HKT and blood density (see figures 29-32; pages 360-362). It would have been obvious to a person of ordinary skill in the art to modify the method and apparatus of WO 98/50091 to include known sensors for measuring TMP, HKT and/or blood density to improve the control of ultrafiltration in the method and apparatus of WO 98/50091.

11. Claim 3 is rejected under 35 U.S.C. 103(a) as being unpatentable over WO 98/50091 as applied to claim 1 above, and further in view of Pedrini et al, Abstract at EDTA/ERA Congress in Madrid (1999)(hereinafter referred to as Pedrini et al). Claim 3 essentially differs from the method of WO 98/50091 in reciting that the infusion rate of the substitution solution supplied upstream of the hemodialyzer and/or hemofilter is preferably increased relative to the infusion rate supplied downstream of the hemodialyzer and/or hemofilter with increasing TMP, increasing blood density and/or increasing HKT. Pedrini et al teach that hemodiafiltration (HDF) with simultaneous pre- and post dilution avoids the risk due to overly high ultrafiltration rate and TMP without affecting solute removal as in pre-HDF and also allows higher ultrafiltration rate and is further ameliorable by optimizing the ratio of pre/post infusion to get higher FF and could be more efficient and safe mode in routine HDF. It would have been obvious to a person of ordinary skill in the art to optimize the pre/post infusion rates of substitution solution to obtain higher ultrafiltration rate and TMP in more efficient and safe mode in routine HDF as suggested by Pedrini et al.

12. Claim 13 is rejected under 35 U.S.C. 103(a) as being unpatentable over WO 98/50091 as applied to claim 1 above, and further in view of German Patent No. 4240681 (hereinafter referred to as Polaschegg). Claim 13 essentially differs from the apparatus of WO 98/50091 in reciting that the means for controlling the infusion rates are valves in the supply lines. Polaschegg teaches a hemodiafiltration apparatus in which pre and post substitution fluid flow is controlled by valves (48, 104) directed by a control unit (58) (see figure 2). It would have been obvious to a person of

ordinary skill in the art to modify the apparatus of WO 98/50091 by incorporating known control scheme with valves in the supply line of substitution fluid to control the infusion rates of the substitution fluid as suggested by Polaschegg.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to John Kim whose telephone number is (703) 308-2350. The examiner can normally be reached on weekdays from 7:00 AM - 3:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Wanda Walker, can be reached on (703) 308-0457. The fax phone number for official response after final action is (703) 872-9311, and the fax phone number for all other official faxes is (703) 872-9310.

When sending a draft amendment by fax, please mark the paper as "DRAFT"; otherwise, mark the paper "OFFICIAL". This will expedite the processing of the paper.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0651.

John Kim
John Kim
Primary Examiner
Art Unit 1723

J. Kim
December 2, 2002